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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,722	10/30/2006	Atsushi Saitou	MOEG-P100	3113

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EXAMINER	
SHTERENGARTS, SAMANTHA L	
ART UNIT	PAPER NUMBER
1626	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,722	SAITOU ET AL.	
	Examiner	Art Unit	
	Samantha L. Shterengarts	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20-27 and 32-34* is/are allowed.

6)☒ Claim(s) *28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted January 28, 2010 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

Status of Claims

2. Claims 20-34 are currently pending and under consideration.

3. All claims are rejoined. Claims 20-27 and 32-34 are allowed.

New Rejections- Necessitated by Amendment

Claim Rejections - 35 USC § 112

4. Claims 28-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a drug which can treat the myriad of conditions encompassed by the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. The nature of the invention
2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present

5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed, and
8. The level of skill in the art

The Nature of the Invention

The claims are drawn to a composition and method for the treatment of a rheumatic disease or a cancer metastatic disease.

There is no disclosure as to how one of ordinary skill in the art could use the instant invention to treat every disease as listed above.

The State of the Prior Art and the Predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases/conditions by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instantly claimed invention is highly unpredictable as discussed below: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of the claimed drugs on the myriad of claimed conditions, determination of whether or not each

condition is affected by the claimed drugs could take a lifetime of experimentation and clinical trials.

The challenge of treating cancer has been to determining target specific therapies to pathogenetically distinct tumor types. Cancer classification has been based primarily on morphological appearance of the tumor. Distinct tumors follow significantly different clinical courses and show different responses to therapy (Golub et al. age 531) (Science (1999), Vol. 286 521-537). Treatment of tumors may include surgery, radiation, chemotherapy, immunotherapy, monoclonal antibody therapy, etc. Additionally, it is known in the prior art (Lala et al. page 91) (Cancer and Metastasis Reviews (1998), 17(1), 91-106) that the role of NO in tumor biology remains incomplete in terms of understanding, with regards to both the promotion and inhibition of NO for the treatment of tumor progression. Only certain cancers may be treated by selected NO-blocking drugs. These examples show that there are different cellular mechanisms in the treatment of cancers, and the unpredictability in the art is high due to the differing treatment protocols. Based on this information, the estrogen dependent cancers as claimed have very different tumors, as well as modes of treatment/inhibition. It is not expected to one of ordinary skill in the art that one compound or in the instant case, class of compounds, will be able to treat these cancers.

Applicant's disclosure does not enable one of ordinary skill in the art to make or use the claimed invention within the entire scope encompassed by the term "cancer." There is no compound, let alone entire classes of compounds, that can reverse, alleviate, prolong the progression of, prevent, or treat the various and divergent cancers, as claimed.

Rheumatic diseases include, but are not limited to Rheumatoid arthritis , Lupus , Sjögren's

syndrome , scleroderma (systemic sclerosis) , dermatomyositis , polychondritis , polymyositis , polymyalgia rheumatica , osteoarthritis , septic arthritis , sarcoidosis , gout, pseudogout , spondyloarthropathies , ankylosing spondylitis , reactive arthritis (aka **reactive arthropathy) , psoriatic arthropathy , enteropathic spondylitis , vasculitis , polyarteritis nodosa , Henoch-Schönlein purpura , serum sickness , Wegener's granulomatosis , giant cell arteritis , temporal arteritis , Takayasu's arteritis , Behçet's syndrome , Kawasaki's disease (mucocutaneous lymph node syndrome) , Buerger's disease (thromboangiitis obliterans) , Juvenile Idiopathic Arthritis(JIA) ; Rheumatic arthritis; Soft Tissue Rheumatism; (Localizes diseases and lesions affecting the joints and structures around the joints including tendons ,ligaments capsules, bursae, Stress Fractures, muscles , nerve entrapment, vascular lesions , ganglion, connective tissue abnormalities and localised Soft tissues disorders etc.), Diseases affecting bones;, Osteoporosis, osteomalacia, renal osteodystrophy, Fluorosis, Rickets Etc., Congenital and familial Disorders affecting Joints;, Hyperextensible joints; Ehlers-Danlos Syndrome,Achondroplasisa, Marfan's Syndrome etc.

The above diseases, as well as the myriad of additional conditions embraced by the claims, are not known to be caused by the same problems, and as such, one of skill in the art would not reasonably expect that therapy for all of the diseases could be accomplished using the same means. Moreover, there are no known agents, or combination of agents, which are known to effectively treat any and all nervous system disorders.

The Amount of Direction / Guidance Present and the Presence or Absence of Working Examples

There is little, if any, direction and guidance present in the instant specification regarding

the use of the claimed compositions for treating the entire scope of diseases as claimed. The only disclosure regarding said treatment is a mere statement that the drug can be used to treat all of the aforementioned disorders. The specification contains absolutely no evidentiary support that the claimed drugs would be able to treat *any* of the diseases encompassed by the claims. The only embodiments/examples described in the specification are disclosures on how to prepare the inventive compositions. There is no disclosure of what receptor the claimed drug might interact with or what cellular mechanism might be affected by the administration of the claimed drugs. There are no examples where the drugs are used to interact with any receptor or cell line *in vitro* or where the drugs are administered to any organism *in vivo*. Furthermore, there are no working examples to support the treatment of any of the claimed diseases.

The breadth of the claims

One drug could not possibly be effective for the treatment of the entire instantly claimed genus of conditions, as evidenced by the unpredictability in the art area regarding the treatment of all disorders as claimed.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine whether the compound exhibits the desired pharmacological activity and which specific pain conditions would benefit from this activity. The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. *In re Fisher*,

839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. *In re Fisher*, 427 F.2d 839, 166 USPQ 24; *Ex Parte Hitzeman*, 9 USPQ 2d 1823.

Thus, the specification fails to provide support for the intended use of the drugs of the instant claims for the treatment of the genus of conditions encompassed by the claims, as a result necessitating one of skill to perform an exhaustive search for which conditions can be treated by the claimed drug in order to practice the claimed invention.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine which disorders would be treated by any of the claimed drugs and would furthermore have to determine which of the claimed drugs would provide treatment of which particular conditions.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated or prevented by the compound encompassed in the instant claims, with no assurance of success.

Conclusion

5. Claims 20-27 and 32-34 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626